IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

RODNEY N. CAFFEY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 2:22-cv-542-MHT-CWB**
	)	
PUBLIX SUPERMARKETS, INC., et al.,	)	
	)	
	)	
Defendants.	)	

RECOMMENDATION OF THE MAGISTRATE JUDGE

Pending before the court are motions for summary judgment by Ohm Laboratories, Inc. (Doc. 88) and Sun Pharmaceuticals, Inc. (Doc. 90). Responses in opposition have been submitted as to both. (*See* Docs. 96 & 98; *see also* Docs. 100 & 101). For the reasons explained below, the Magistrate Judge recommends that summary judgment be entered in favor of Ohm and Sun as requested.

I. Procedural History and Factual Background

Rodney N. Caffey filed this action in state court to seek redress for injuries allegedly sustained from taking the prescription medication Atorvastatin. (*See* Doc. 2-1 at pp. 11-22). Proceedings were properly removed (*see* Doc. 2), and the court continues to have jurisdiction under 28 U.S.C. § 1332(a) (*see* Doc. 50 at p. 8). In his most recent Amended Complaint, Caffey alleges twenty total causes of action—seven of which seek relief from Ohm and Sun:

- Claim 8: Medical Malpractice (Doc. 73 at pp. 20-22);
- Claim 9: Alabama Extended Manufacturer's Liability Doctrine (*Id.* at pp. 22-23);
- Claim 10: Breach of Implied Warranty (*Id.* at pp. 23-24); and
- Claims 11 through 14: Products Liability (*Id.* at pp. 24-28).

The relevant facts surrounding those claims are not in dispute.

According to Caffey, he acquired 10mg Atorvastatin tablets in 30-day increments beginning in approximately 2018. (Doc. 97 at p. 2, ¶¶ 1-2; Doc. 97-2 at p. 11; Doc. 73 at ¶ 16). From early 2018 through May 2020, Caffey tolerated the medication without incident and admittedly "had never encountered a problem with Atorvastatin usage." (Doc. 97 at p. 2, ¶ 3). On May 23, 2020, Caffey for the first time acquired a 90-day supply of 10mg Atorvastatin tablets. (Doc. 97 at p. 2, ¶ 4; Doc. 97-2 at p. 7; Doc. 73 at ¶ 64).

Caffey asserts that "[o]n or about July 7, 2020, [he] 'ran-out' of the 90 day supply of Atorvastatin, and then he had the prescription refilled, as a 30 day supply, and began ingesting the tablets daily." (Doc. 97 at p. 2, ¶ 5; Doc. 73 at ¶¶ 24, 76). Caffey alleges that "after ingesting the tablets from the July 2020 prescription, … he began to experience adverse side-effects, as a result of the allegedly defective/mislabeled tablets;" specifically, "he began to notice a 'searing sensation' in his legs/lower extremities, [and] numbness in his back, elbows, and eyelids." (Doc. 97 at ¶¶ 6-7; Doc. 73 at ¶¶ 22-23, 77). Caffey states that "he took 16.5 tablets from his 30 day supply, leaving him with 13.5 tablets remaining" (Doc. 97 at pp. 2-3, ¶ 8; Doc. 73 at ¶ 76), and that he discontinued taking Atorvastatin "for good" as of July 31, 2020 (Doc. 97 at p. 3, ¶ 9; Doc. 73 at ¶ 25).

Caffey admits that "[o]n November 22, 2022, [he] brought the '13.5 ill-fated' tablets he had remaining from his July 2020 prescription to a pre-discovery meeting, at the offices of Alabama Court Reporting, Inc., for examination, with a court reporter, and photographer present." (Doc. 97 at p. 4, ¶ 14; *see also* Doc. 89-1). Stated differently. Caffey has acknowledged that "the tablets that he brought with him, were what is left from the prescription he avers contained defective/misbranded tablets." (Doc. 97 at p. 4, ¶ 15; *see also* Doc. 89-3). Photographs from the November 22, 2022 meeting show that each of the 13.5 pills was white in color, oblong in shape,

and contained the markings "I 4" on one side and no markings on the opposing side. (Doc. 89-1 at pp. 9-12).

Caffey claims that the Atorvastatin tablets causing his adverse reaction in July 2020 were manufactured by Ohm and distributed by Sun. (Doc. 91 at p. 1; *see also* Doc. 73 at ¶¶ 19-25, 76-77, 148-50). The record reflects that Ohm indeed is "involved in the manufacturing and distribution of certain pharmaceutical products" (*see* Doc. 77 at p. 2, ¶ 9), including Atorvastatin (*id*. at p. 23, ¶ 157), and that Sun likewise is "involved in the distribution of certain pharmaceutical products" (*see* Doc. 88 at p. 2, ¶ 11), including Atorvastatin (*id*. at p. 23, ¶ 157). The record additionally reflects that Sun is the parent corporation of Ohm. (*See* Doc. 77 at p. 2, ¶ 9).

Daryl LeSueur, in his capacity as Vice President, Head of Operations, North America for Ohm, has executed a sworn affidavit stating that he "reviewed the photographs of the pills produced by Mr. Caffey for inspection on November 22, 2022" and that "[t]he pills in the photographs are definitely not Atorvastatin pills manufactured by Ohm, nor do the markings on the pills match any other medications manufactured by Ohm." (Doc. 89-2 at p. 3). LeSueur attached photographs as exhibits to his affidavit showing the front and back sides of the 10mg and 20mg Atorvastatin tablets that Ohm does manufacture. (Doc. 89-2 at pp. 4-7). For the 10mg tablets, identified in Exhibits A and B, the photographs depict white, elliptical tablets with the markings "RX 12" on one side and no markings on the opposing side. (*Id.* at pp. 4-5). For the 20mg tablets, identified in Exhibits C and D, the photographs depict white, elliptical tablets with the markings "RX 828" on one side and no markings on the opposing side. (*Id.* at pp. 6-7). Sun similarly submitted a declaration under penalty of perjury from Parshotamdas Judgelal Deepak as its Head of Quality, North American Cluster. (Doc. 91-2 at p. 2). Deepak testified that he also had reviewed the photographs of Caffey's medication and could "confirm that the pills in

those photos do not depict Atorvastatin distributed by Sun Pharmaceutical Industries, Inc." (*Id.*). Deepak further testified that the markings shown in the exhibits to LeSueur's affidavit "accurately depict the Atorvastatin tablets distributed by Sun Pharmaceutical Industries, Inc." and that the "markings on those tablets have remained the same since 2011." (*Id.*).[1]

II. Summary Judgment Standard

Summary judgment is appropriate when the moving party shows that there is no genuine dispute as to any material fact and that it is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). A dispute "is 'genuine' if the record as a whole could lead a reasonable trier of fact to find for the nonmoving party … . [A fact] is 'material' if it might affect the outcome of the case under the governing law." *Redwing Carriers, Inc. v. Saraland Apartments*, 94 F.3d 1489, 1496 (11th Cir. 1996) (citation omitted).

The party moving for summary judgment "always bears the initial responsibility of informing the district court of the basis for the motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). That responsibility includes identifying the portions of the record illustrating the absence of a genuine dispute of material fact. *Id.* Alternatively, a movant who does not have a trial burden of production can simply assert that the nonmoving party "cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(B); *see also* Fed. R. Civ. P. 56 advisory committee's note ("Subdivision (c)(1)(B) recognizes that a party need not always point to specific record materials. … [A] party who does not have the trial burden of production may

[1] Caffey submitted numerous receipts for his purchases of Atorvastatin that reflect tablets manufactured by "OHM-SUN PHARMAC." (*See* Doc. 97-2). Consistent with the affidavits provided by Ohm and Sun, the receipts submitted by Caffey reflect that the tablets were "white" in color and "elliptical" in shape, with a marking of "RX 12" on Side 1 and no marking on Side 2. (*Id.*). No such receipt, however, has been submitted for the July 2020 refill that was visually different and allegedly resulted in Caffey's adverse reaction.

rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact."). Under either scenario, the burden then shifts to the nonmoving party to establish that a genuine dispute of material fact exists as to each element of the underlying claims. *See Celotex Corp.*, 477 U.S. at 324; *see also* Fed. R. Civ. P. 56(c)(1)(A).

To establish a genuine dispute of material fact, the nonmoving party must produce such evidence as would be sufficient for a reasonable trier of fact to return a verdict in its favor. *See Waddell v. Valley Forge Dental Assocs., Inc.*, 276 F.3d 1275, 1279 (11th Cir. 2001). When evaluating whether a genuine dispute of material fact exists, the court must view all of the evidence in a light most favorable to the nonmovant and draw all justifiable inferences from the evidence in the nonmovant's favor. *See McCormick v. City of Fort Lauderdale*, 333 F.3d 1234, 1243 (11th Cir. 2003); *see also* Fed. R. Civ. P. 56(a). Nonetheless, "[w]hen opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment." *Scott v. Harris*, 550 U.S. 372, 380 (2007).

Although *pro se* complaints are entitled to liberal interpretation, a *pro se* litigant is not relieved from the burden of demonstrating a genuine dispute of material fact in response to a motion for summary judgment. *Beard v. Banks*, 548 U.S. 521, 525 (2006); *Brown v. Crawford*, 906 F.2d 667, 670 (11th Cir. 1990).

III. Discussion[2]

Ohm and Sun have both offered evidence from competent representatives within their respective companies stating that the 13.5 tablets produced by Caffey at the evidentiary meeting

[2] The briefs filed by Ohm and Sun are materially identical as to all issues presented. (*Cf.* Doc. 89 at pp. 7-15 & Doc. 91 at pp. 6-15). Accordingly, the arguments presented by Ohm and Sun will be addressed together.

were not manufactured by either of them—as evidenced by distinct markings on the tablets that do not appear on any medication manufactured or distributed by Ohm or Sun. (Doc. 89-2 at p. 3; Doc. 91-2 at p. 2). In response to those affidavits, Caffey asserts as follows:

> The Plaintiff specifically Objects to the conclusory statements, and unsubstantiated documents, presented on behalf of the two above-named individuals as being: pursuant to Alabama Rules of Evidence, Section 801(c), excludable Hearsay statements made outside the present proceedings, used ostensibly to prove the truth of the matter asserted.

(Doc. 97 at p. 5; *see also* Doc. 99 at p. 5).

To the extent Caffey objects to the LeSueur and Deepak affidavits on the basis of hearsay, his objection is due to be overruled. Rule 56(c)(1) of the Federal Rules of Civil Procedure expressly authorizes parties to support their assertions by "affidavits or declarations." The only caveat is that "[a]n affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4). Caffey fails to offer any challenge to the LeSueur or Deepak affidavits on those grounds. Accordingly, Caffey's objections to the LeSueur and Deepak affidavits as "hearsay" are overruled.[3]

With respect to the substance of the affidavits, Caffey fails to offer any competing evidence or argument that would create a genuine issue of material fact for trial. Rather, Caffey makes only

[3] Rule 56(c)(3) also provides that "[a] party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." *See also Macuba v. Deboer*, 193 F.3d 1316, 1322 (11th Cir. 1999) ("The general rule is that inadmissible hearsay cannot be considered on a motion for summary judgment …, but a district court may consider a hearsay statement in passing on a motion for summary judgment if the statement could be reduced to admissible evidence at trial or reduced to admissible form.") (internal quotation marks and footnote omitted). The Magistrate Judge finds that the relevant testimony and photographs from the LeSueur and Deepak affidavits would be readily reducible to admissible evidence for trial. *See also* Fed. R. Civ. P. 56(c)(4) (permitting consideration of affidavits that "set out facts that would be admissible in evidence").

speculative musings about pills moving in the "grey market," a product recall from years before the alleged injury, and theoretical sabotage by disgruntled employees. (Doc. 99 at pp. 4-5). It consistently has been held that such "conclusory allegations without specific supporting facts have no probative value." *See Evers v. General Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985). Instead, "the nonmoving party's response must set forth specific facts showing a genuine issue for trial." *Barfield v. Brierton*, 883 F.2d 923, 934 (11th Cir. 1989); *see also* Fed. R. Civ. Proc. 56(e)(3) ("If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c), the court may … grant summary judgment if the motion and supporting materials—including the facts considered undisputed—show that the movant is entitled to it.").

In response to the properly supported motions for summary judgment here, Caffey has failed to provide any affidavits or "specific facts" that would tend to refute the averments that the 13.5 tablets produced at the evidentiary meeting were not manufactured by Ohm or Sun. Put more simply, when confronted with verified testimonial and photographic evidence that all Atorvastatin pills manufactured and distributed by Ohm and Sun since 2011 have been elliptical in shape with markings of "RX 12" or "RX 828," Caffey offered no opposing evidence to suggest that the 13.5 oblong pills with "I 4" markings were nevertheless Atorvastatin tablets manufactured by Ohm and distributed by Sun.

On such a factual record, Caffey's claims against Ohm and Sun are readily resolved under Ala. Code § 6-5-530:

> (a) In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product. Designers, manufacturers, sellers, or lessors of products not identified as

> having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury. A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable.

Ala. Code § 6-5-530(a) (emphasis added). In applying the statute, the Alabama Supreme Court has recognized its expansive effect:

> … [Section] 6-5-530 specifically provides that a plaintiff who is suing based on personal injury, death, or property damage caused by a product "must prove ... that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based" regardless of the type of claims or theory of liability the plaintiff asserts. It goes on to provide … "that ... manufacturers ... of products not identified as having been ... ingested ... by an allegedly injured party may not be held liable for any alleged injury."

Forest Lab'ys, LLC v. Feheley, 296 So. 3d 302, 314-15 (Ala. 2019) (emphasis in original). The court thus held that "under the plain language of § 6-5-530, a pharmaceutical manufacturer cannot be held liable for injury caused by a product it did not manufacture." *Id*. at 316. *See also Blackbrun v. Shire U.S., Inc.*, 380 So. 3d 354, 360 n.1 (Ala. 2022) ("[U]nder the plain language of § 6-5-530, a pharmaceutical manufacturer cannot be held liable for injury caused by a product it did not manufacture.") (quoting *Feheley*, 296 So. 3d at 316).

It is undisputed that Ohm and Sun did manufacture 10mg Atorvastatin tablets that were dispensed to Caffey at various times. (*See* Doc. 97-2). But the only tablets alleged to have caused injury to Caffey are those he received and ingested during July 2020. (*See* Doc. 97 at p. 2, ¶¶ 6-7 & Doc. 89-3). The July 2020 tablets do not match the appearance of the tablets manufactured and distributed by Ohm and Sun, and both Ohm and Sun have presented verified evidence that they did not manufacture or distribute the tablets alleged to have caused injury (*see* Docs. 89-2 & 91-2). Caffey has presented no evidence to the contrary. Pursuant to Ala. Code § 6-5-530, he therefore cannot proceed on any of the claims asserted against Ohm or Sun.

IV. Conclusion

Accordingly, the Magistrate Judge hereby **RECOMMENDS** as follows:

1. that the Motion for Summary Judgment (Doc. 88) filed by Ohm Laboratories, Inc. be granted;

2. that the Motion for Summary Judgment (Doc. 90) filed by Sun Pharmaceuticals, Inc. be granted; and

3. that proceedings be referred back to the Magistrate Judge on all remaining claims against all remaining defendants.

It is **ORDERED** that all objections to this Recommendation must be filed no later than **September 19, 2024**. An objecting party must identify the specific portion(s) of factual findings/ legal conclusions to which objection is made and must describe in detail the basis for each objection. An objecting party also must identify any claim or defense that the Recommendation has not addressed. Frivolous, conclusive, or general objections will not be considered.

After receiving objections, the District Judge will conduct a *de novo* review of the findings or recommendations to which objection is made. The District Judge may accept, reject, or modify the Recommendation or may refer the matter back to the Magistrate Judge with instructions for further proceedings. *See* 28 U.S.C. § 636(b)(1)(C). A party shall be deemed to have waived the right to challenge on appeal a District Judge's order to the extent it is based upon unobjected-to findings or recommendations. The court on appeal may review unobjected-to factual and legal conclusions only for plain error if necessary in the interests of justice. *See* 11th Cir. R. 3-1.

No party may appeal this Recommendation directly to the United States Court of Appeals for the Eleventh Circuit. An appeal may be filed only in response to an appealable order entered by the District Judge.

DONE this the 5th day of September 2024.

CHAD W. BRYAN
UNITED STATES MAGISTRATE JUDGE